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EXAMINER	
CHAMBERS, J	
ART UNIT	PAPER NUMBER

1804  
DATE MAILED:

04/01/96

This is a communication from the examiner in charge of your application.  
**COMMISSIONER OF PATENTS AND TRADEMARKS**

☐ This application has been examined ☒ Responsive to communication filed on 12/8/95 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 4/10/83 month(s), — days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

1. ☐ Notice of References Cited by Examiner, PTO-892. 2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-048.
3. ☐ Notice of Art Cited by Applicant, PTO-1449. 4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.. 6. ☐

## Part II SUMMARY OF ACTION

1. ☒ Claims 1-28, 41-53, 55-72, 74-95, 99-118, 123, 125, 126 and 128 are pending in the application.
- Of the above, claims 1-28, 41-53, 55-72, 74-81, 84-95 are withdrawn from consideration.
2. ☒ Claims 73, 119-122, 124 and 127 have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☒ Claims 82, 83, 97-118, 123, 125, 126 and 128 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1835 C.D. 11; 453 O.G. 213.
14. ☐ Other \_\_\_\_\_

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 120-127 under 35 U.S.C. 112, second paragraph, as set forth on page 2 of the last Office action, is withdrawn in view of Applicants' amendments to the claims in the Amendment filed December 8, 1995.

The objection to the specification and the rejection of claim 73 under 35 U.S.C. 112, first paragraph, as set forth on page 2 of the last Office action, are withdrawn in view of Applicants' cancellation of the claim in the Amendment filed December 8, 1995.

The rejection of claims 73, 82, 83, 97-127 under 35 U.S.C. 112, first paragraph, as set forth on pages 2-3 of the last Office action, is withdrawn in view of the Janne Declaration filed December 8, 1995 and Applicants' arguments and amendments to the claims in the Amendment filed December 8, 1995.

Claims 82, 83, 97-118, 123, 125 and 126, newly amended, and claim 128, newly added, are rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Applicants' claimed invention is unclear because the claims now recite "a transgenic bovine species". Do the claims encompass species other than cattle? If so, it is not evident that species other than cattle are in fact enabled by the specification, especially in light of Applicants' arguments in their rebuttal to the prior art rejections.

The rejection of claims 120 and 121 under 35 U.S.C. 102(b) or 103 as set forth on page 4 of the last Office action, is withdrawn in view of Applicants' cancellation of the claims in the Amendment filed December 8, 1995.

The rejection of claims 73, 82, 83, 97-121 under 35 U.S.C. 103 as set forth on pages 5-6 of the last Office action, is withdrawn in view of Applicants' amendments to the claims in the Amendment filed December 8, 1995.

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The rejection of claims 73, 82, 83, 97-121 under 35 U.S.C. 103 as set forth on pages 6-7 of the last Office action, is withdrawn in view of Applicants' amendments to the claims in the Amendment filed December 8, 1995.

Claims 82, 83, 97-118, 123, 125 and 126, newly amended, remain rejected, and claim 128, newly added, is rejected under 35 U.S.C. 103 as being unpatentable over any one of Meade et al. ('316 patent), Hopp (B6) or Gordon et al. (EPA), when taken with First et al. ('979 patent), as applied in the last Office action mailed May 2, 1995.

Claims 82, 83, 97-118, 123, 125 and 126, newly amended, remain rejected, and claim 128, newly added, is rejected under 35 U.S.C. 103 as being unpatentable over any one of Meade et al. ('316 patent), Hopp (B6) or Gordon et al. (EPA), when taken with any one of Loskutoff et al. (C37), Biery et al. (C31) or Bondioli et al. (C32), and further in view of First et al. ('979 patent), as applied in the last Office action mailed May 2, 1995.

Claims 82, 83, 97-118, 123, 125 and 126, newly amended, remain rejected, and claim 128, newly added, is rejected under 35 U.S.C. 103 as being unpatentable over any one of Simons et al. (C38), Clark et al. (C35), Gordon et al. (C36) or Bremel et al. (C34), when taken with any one of Loskutoff et al. (C37), Biery et al. (C31) or Bondioli et al. (C32), and further in view of First et al. ('979 patent), as applied in the last Office action mailed May 2, 1995.

Applicant's arguments on pages 11-16 of the Amendment, the Janne Declaration, and the First Declaration, all filed on December 8, 1995, have been carefully considered but are not deemed fully persuasive. Applicants argue that the success of their claimed method represents an unexpected result and cite the Janne Declaration and the First Declaration in support. Applicants further assert that the efficiency of their claimed method is unexpectedly high. However, in the absence of a side-by-side comparison, the Examiner cannot readily evaluate or compare the efficiencies of the in vitro and in vivo methods. Moreover, in view of the 112 issues raised by the use of the term "species" in the claims (see the rejection above), as well as Applicants' argument for unexpected results, the rejections are maintained to the extent that the claims are not limited to the single species of cattle.

No claim is allowed.

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Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

This application contains claims 1-28, 41-53, 55-72, 74-81 and 84-95 drawn to an invention non-elected without traverse in Paper No. 9. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (37 C.F.R. § 1.144) M.P.E.P. § 821.01.

This application is subject to the provisions of Public Law 103-465, effective June 8, 1995. Accordingly, since this application has been pending for at least two years as of June 8, 1995, taking into account any reference to an earlier filed application under 35 U.S.C. 120, 121 or 365(c), applicant, under 37 CFR 1.129(a), is entitled to have a first submission entered and considered on the merits if, prior to abandonment, the submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a first submission and the appropriate fee of \$365 for a small entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

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If applicant has filed multiple proposed amendments which, when entered, would conflict with one another, specific instructions for entry or non-entry of each such amendment should be provided upon payment of any fee under 37 CFR 1.17(r).

Any inquiry concerning this communication should be directed to Jasemine C. Chambers, Ph. D., at telephone number (703) 308-2035.

*Jasemine C. Chambers*  
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